NOV 0 7 2001

K013521

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: Coleen Coleman
Tel: (408) 468-3051
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B. Device Trade Name: GEMINI
Common Name: Positron Emission Tomography
Computed Tomography X-Ray
Classification Name: System, Emission Computed Tomography, (892.1200)
System, Computed Tomography X-Ray, (892.1750)
Device Class: 21CFR 892.1200, Class II
21 CFR 892.1750, Class II
Product Code: 90 KPS and 90 JAK

C. Date prepared: October 5, 2000

D. Predicate Device: ~~GE CT-PET (K01064T)~~ ADAC Allegro PET, K003434
~~EXACT CT-PET (K002715)~~ Marconi MX 8000 CT, K010817

E. Performance Standards 21 CFR 1020.30 – 1020.33 as applicable for Computed Tomography X-Ray, (892.1750)

E. Intended Use:

GEMINI is an imaging system that combines positron emission tomography (PET) and X-ray computed tomography. The GEMINI produces attenuation and non-attenuation corrected images of the distribution of PET radiopharmaceuticals in the head, body and total body as well as x-ray transmission images of these areas. The PET and CT images are registered and displayed in a "fused" format to provide combined PET and anatomical data at different angles for interpretation by trained health professionals. The PET and CT portions of the system can be used either as an integrated system or as a stand-alone PET or CT system. GEMINI can provide CT data suitable for use in attenuation correction.

F. Device Description:

The GEMINI hybrid PET/CT system is a combined positron emission tomography and X-ray computed tomography scanner. This system uses the ADAC ALLEGRO PET system, K003434, and the Marconi Medical Systems MX8000-v5.0 CT, K010817. The GEMINI integrates the two system operator consoles into a single workstation to allow straightforward planning and system operation. The ALLEGRO PET and the MX8000 CT system gantries remain intact as major subsystem components located within a common integrated housing. It can be used in any clinical protocols and procedures, which have been clinically conducted in a separate CT system and/or a PET system. No modifications have been made to either system, which would affect system performance.

GEMINI is intended for use primarily as a clinical whole body oncology scanner with high-end dual slice CT capability and high-end GSO based PET performance. It mechanically separates to allow for the greater flexibility for above three operation modes. The availability of

low dose tomographic data sets implies that a natural extension of the ALLEGRO based cesium source attenuation correction to a CT transmission map attenuation correction exists. The primary purpose, however, of the CT is to provide precise anatomical localization for the metabolically significant positron emission distributions imaged on the PET system. These images when properly registered and displayed as a fused image, provide both functional and anatomical information with reliable spatial correspondence in a single image.

G. Comparison to Predicate Device:

The predicate devices, GE CT-PET (Discovery LS) and the ECAT CT-PET (Biograph) are similar to the GEMINI in that all of the devices consist of a full functional CT and PET. The patient may have a diagnostic CT and PET scan performed consecutively without having to move the patient. The GEMINI provides a mean to reach the diagnostic decision faster than the conventional way of imaging patients with both CT and PET systems in separate locations. The differences are the area of overall system dimensions, room size requirements, scanning length, and ease of use.

The GEMINI CT-PET is designed so that the system can operate in three modes: CT only, PET only and combined CT/PET. The major difference is that the GEMINI imaging system has a separation system that allows the distance of the CT and PET units to be increased. This feature provides easy access to the patient. GEMINI provides a newly developed dedicated PET/CT table to minimize the system room requirements

H. System Performance Test:

- The MX 8000 v.5.0 is manufactured in accordance with Performance Standards in 21 CFR 1020.30 – 33.
- ALLEGRO system performance was measured according to the NEMA-NU2 standard. In addition, clinical phantoms with clinical protocols were used to evaluate ALLEGRO image quality in terms of the noise texture and contrast of the image.
- The GEMINI complies with voluntary standards for safety and effectiveness (IEC 60601-1, IEC 60601-2, IEC 60825-1, UL 2601-1, & CAN/CSA-C22.2 and is tested to demonstrate the hazards, i.e., electrical, mechanical, and radiation have been minimized.

I. Conclusion:

The GEMINI Imaging System is substantially equivalent to the predicate devices, the GE CT-PET (K010641) and the EXACT CT-PET (K002715) based upon similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

ADAC Laboratories
% Michael Kwan, Ph.D.
Principal Reviewer/Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K013521
Trade/Device Name: GEMINI PET-CT Device
Combined PET/CT System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS
Product Code: 90 JAK
Dated: October 22, 2001
Received: October 23, 2001

Dear Dr. Kwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 0 7 2001

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K013521

DEVICE NAME: GEMINI

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

GEMINI is an imaging system that combines positron emission tomography (PET) and X-ray computed tomography. The GEMINI produces attenuation and non-attenuation corrected images of the distribution of PET radiopharmaceuticals in the head, body and total body as well as x-ray transmission images of these areas. The PET and CT images are registered and displayed in a "fused" format to provide combined PET and anatomical data at different angles for interpretation by trained health professionals. The PET and CT portions of the system can be used either as an integrated system or as a stand-alone PET or CT system. GEMINI can provide CT data suitable for use in attenuation correction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013521